REMARKS

Reconsideration and allowance of the subject application are requested.

We first thank the Examiner for the courtesies extended to Applicants' representative during the telephone conversation on December 22, 2003, during which the outstanding Office Action was discussed.

Claims 28 and 49 are amended to specify that when the composition is administered to a mammal both G1 glycoprotein and G2 glycoprotein are expressed in an amount effective to confer protective immunity against Hantavirus infection. Claim 37 is amended to specify that step (b) entails accelerating the inert particle of (a) into epidermal cells of a mammal in vivo, under conditions that both G1 glycoprotein and G2 glycoprotein are expressed in an amount effective to generate an immune response sufficient for protection in the mammal against a challenge by a hantavirus of the same species as the hantavirus protein and the hantavirus M gene segment are derived from. Claim 48 is amended to specify that step (b) entails accelerating the particles of (a) into epidermal cells of the mammal in vivo under conditions that both G1 glycoprotein and G2 glycoprotein are expressed in an amount effective to generate an immune response sufficient for protection in the mammal to a hantaviral challenge of the Seoul virus, the Dobrava virus and/or the Hantaan virus. Support for these revisions is found throughout the original disclosure, for instance, in the examples section. No new matter is introduced by any of this amendatory language. Entry into the record of the amended claim is requested.

In the September 24, 2003 Office Action, the Examiner indicated that the subject matter of claims 33, 34, 42, 43, 50 and 51 is allowable.

However, claims 28-32, 35-41, 44, 45, 48 and 49 are rejected under 35 U.S.C. §103(a), as obvious over the combination of the following five references: (1) Schmaljohn (Rev. Med. Virol., 4:185-196, 1994); (2) Chu et al., (J. Virol., 69(10):6417-6423, 10/95); (3) Arikawa et al., (Virol, 176:114-125, 1990); (4) Montgomery et al., (Pharmacol. Ther., 74(2):195-205, 1997); and (5) Donnelly et al., (Ann. Rev. Immunol., 15:617-648, 1997).

With our Amendment filed June 30, 2003 we submitted a Rule 132 Declaration which provided evidence that the expression of both G1 and G2 glycoproteins are needed to confer protective immunity, and that just one alone is insufficient. In light of the teachings of the cited art, this represents unexpected results achieved by the use and practice of the invention.

In the Amendments to independent claims 28, 37, 48 and 49 above, we have affirmatively recited (in the composition claims) that when the inventive composition is administered to a mammal both G1 glycoprotein and G2 glycoprotein are expressed in an amount effective to confer protective immunity against Hantavirus infection; or (in the method claims) that step (b) entails accelerating the inert particle of (a) into epidermal cells of a mammal in vivo, under conditions that both G1 glycoprotein and G2 glycoprotein are expressed in an amount effective to generate an immune response sufficient for protection in the mammal against a challenge by a hantavirus of the same species as the hantavirus protein and the hantavirus M gene segment are derived from (which, in the case of claim 49, is the Seoul, Dobrava and/or Hantaan virus). In other words, our invention requires the expression in vivo of both G1 and G2 glycoproteins in sufficient amount to be effective to confer protective immunity against Hantavirus infection—which is something none of the cited references suggest at all. At best, the cited references describe the expression of only one of either G1 or G2 glycoprotein. None of the five references, alone or combined, would have lead someone having ordinary skill in this art to reasonably expect that a composition including an inert particle coated with a polynucleotide encoding a G1 glycoprotein and a G2 glycoprotein, when administered to a mammal, would confer protective immunity against Hantavirus when both G1 glycoprotein and G2 glycoprotein are expressed in an effective amount.

In the Office Action the Examiner requested additional information regarding the experiments referenced in the Rule 132 Declaration. In particular, the Examiner maily inquired whether the immunization was done with a composition where the polynucleotide is coated onto inert particles (i.e., using the composition as presently claimed). The answer is yes: the DNA vaccines comprised of polynucleotides coated onto gold beads, administered using a gene gun.

In summary, we believe the Rule 132 Declaration provides the Examiner with the evidence that clearly distinguishes our claimed invention from any of the cited references, taken alone or in combination with each other. In addition, the amendments to the independent claims affirmatively recite that the combination of G1 and G2 glycoproteins when both are expressed in a mammal following administration of the polynucleotide on an inert particle, will confer protective immunity to Hantavirus infection. In summary then, the combined disclosures of Schmaljohn, Chu, Arikawa, Montgomery and Donnelly to arrive at the compositions and methods of our claimed invention. Therefore, we submit that none of claims 28-32, 35-41, 44, 45, 48 and 49 would have been obvious at the time of our invention, in light of the five references cited by the Examiner. Reconsideration and withdrawal of this rejection is requested.

Having addressed all of the Examiner's outstanding concerns, it is believed that this application is in condition for allowance, and notice of such is earnestly solicited. No amendment made was related to the statutory requirements of patentability unless expressly stated herein, and no amendment made was for the purpose of narrowing the scope of any claim unless we argued above that such amendment was made to distinguish over a particular reference or combination of references.

If the Examiner has any questions or would like to make suggestions as to claim language, he is encouraged to contact Marlana K. Titus at (301) 977-7227. **Please note that this is a new telephone number.**

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